IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

ABBVIE INC., et al., *Plaintiffs*, v. LIZ MURRILL, in her official capacity as Attorney General of Louisiana, *Defendant*.	**Case No. 6:23-cv-01307** **JUDGE: Robert R. Summerhays** **MAGISTRATE JUDGE: Carol B. Whitehurst**

MEMORANDUM IN SUPPORT OF MOTION TO INTERVENE BY THE LOUISIANA PRIMARY CARE ASSOCIATION

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INTRODUCTION

In June 2023, Louisiana enacted Act 358 of 2023 ("Act 358") (codified at La. Stat. Ann. §§ 40:2881 to 2886), which requires pharmaceutical manufacturers to ship drugs discounted under the federal 340B drug pricing program ("340B Program") to pharmacies under contract with Louisiana safety-net providers. Plaintiffs in this lawsuit seek an order declaring Act 358 invalid as well as an injunction against enforcement of Act 358. Act 358 was enacted to protect Louisiana safety-net providers, yet no health care provider is a party to this action. The Louisiana Primary Care Association ("LPCA" or "Proposed Intervenor") represents the interests of the law's intended beneficiaries. Members of LPCA participate in the 340B Program and rely on contract pharmacy arrangements to meet the pharmacy needs of their patients. LPCA is, therefore, entitled to intervene under Federal Rule of Civil Procedure 24(a) because it has a significant interest in the subject matter of this action that could be impaired by the disposition of the litigation, and no party completely and adequately represents its interests. Alternatively, the Court should grant permissive intervention under Rule 24(b) because LPCA has claims and defenses that share commons questions of law and fact with the action, and its intervention will not cause undue delay or prejudice to the parties.

This action is in its infancy. On December 7, 2023, the Parties filed a Joint Motion to Set Briefing Schedule, ECF No. 21, and on December 11, 2023, the Court granted the motion and established summary judgment briefing deadlines in this case, ECF No. 22. LPCA will comply with the deadlines applicable to Defendant in the Court's December 11, 2023, order. LPCA notes that this Court granted LPCA's motions to intervene in two similar actions challenging Act 358 and respectfully suggests that the Court should also grant LPCA's motion in this case. Order Granting Motion to Intervene, *Pharm. Rsch. & Mfrs. of Am. v. Landry*, No. 6:23-cv-00997-RRS-CBW (W.D. La. Nov. 8, 2023), ECF No. 26; Order Granting Motion to Intervene,

AstraZeneca Pharm. LP v. Landry, No. 6:23-cv-01042-RRS-CBW (W.D. La. Nob. 9, 2023), ECF No. 29.

BACKGROUND

I. Legal Background

A. Intervention

1. Mandatory Intervention

Under Rule 24(a), a party may intervene as a matter of right if it "claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest." Fed. R. Civ. P. 24(a)(2). Rule 24(a) thus requires a proposed intervenor to satisfy a four-part test: 1) the application for intervention must be timely; 2) the applicant must have an interest relating to the property or transaction which is the subject of the action; 3) the applicant must be so situated that the disposition of the action may, as a practical matter, impair or impede the applicant's ability to protect that interest; and 4) the applicant's interest must be inadequately represented by the existing parties to the suit. *Guenther v. BP Ret. Accumulation Plan*, 50 F.4th 536, 542 (5th Cir. 2022); *Entergy Gulf State La., LLC v. EPA*, 817 F.3d 198, 203 (5th Cir. 2016).

The Fifth Circuit has a "broad policy favoring intervention" and has made clear that Rule 24 is to be liberally construed. *Wal-Mart Stores, Inc. v. Tex. Alcoholic Beverage Comm'n*, 834 F.3d 562, 569 (5th Cir. 2016). Furthermore, doubts as to whether intervention is appropriate are to be "resolved in favor of the proposed intervenor." *In re Lease Oil Antitrust Litig.*, 570 F.3d 244, 248 (5th Cir. 2016) (citation omitted).

Rule 24(a)(2) requires only that an intervenor "'claim[] an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may

as a practical matter impair or impede the movant's ability to protect its interest . . . .'" *Guenther*, 50 F.4th at 542 (quoting Fed. R. Civ. P. 24(a)(2)). A person claiming an interest in the litigation need not wait until he or she has suffered irreparable harm before the requirements for intervention under Rule 24(a) have been met. *In re Lease Oil Antitrust Litig.*, 570 F.3d at 251 ("[P]ossibility of a practical harm to [Intervenor's] interest . . . is sufficient to show impairment."). If the effect of an adverse ruling would have a negative stare decisis effect on a proposed intervenor's interests, that impact would provide the requisite type of impairment to warrant intervention of right. *See id.* (finding that a court order is sufficient to show impairment); *see also Brumfield v. Dodd*, 749 F.3d 339, 344 (5th Cir. 2014) ("The very purpose of intervention is to allow interested parties to air their views so that a court may consider them before making potentially adverse decisions.").

A proposed intervenor typically has a "minimal" burden of showing that its interests are not adequately represented by the parties. *Entergy Gulf States La.*, 817 F.3d at 203; *Rotstain v. Mendez*, 986 F.3d 931, 939 (5th Cir. 2021) ("A movant's burden to show that its interests are not adequately protected is minimal and satisfied if the applicant shows that representation of his interest may be inadequate.") (internal quotations omitted). A proposed intervenor can rebut the general presumption that the government is adequately representing its interests by showing that its interests actually differ from, or conflict with, the government's interests. *Brumfield*, 749 F.3d at 346; *Texas v. United States*, 805 F.3d 653, 662 (5th Cir. 2015).

2. Permissive Intervention

Permissive intervention under Rule 24(b) provides that "[o]n timely motion, the court may permit anyone to intervene who . . . has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1), (b)(1)(B). The decision to grant or deny a motion for permissive intervention is wholly discretionary, but the Fifth Circuit construes

motions to intervene liberally. *United States ex rel. Hernandez v. Team Fin., LLC*, 80 F.4th 571, 577 (5th Cir. 2023); *Wal-Mart Stores*, 834 F.3d at 565. The principal factor that courts consider in ruling on a Rule 24(b) permissive intervention motion is whether the proposed intervention would "unduly delay or prejudice the adjudication of the rights of the original parties." *Newby v. Tex. State Bd. of Pub. Acct.*, 443 F.3d 416, 424 (5th Cir. 2006).

3. Timeliness

Rule 24 requires that a motion to intervene be "timely." Fed. R. Civ. P. 24(a), (b)(1). Deciding the timeliness of intervention "is not limited to chronological considerations but is to be determined from all the circumstances." *Wal–Mart Stores*, 834 F.3d at 565 (quoting *Stallworth v. Monsanto Co.*, 558 F.2d 257, 263 (5th Cir. 1977) (internal quotations omitted)). There are "no absolute measures of timeliness." *Edwards v. City of Houston*, 78 F.3d 983, 1000 (5th Cir. 1996). It is a flexible standard left to the discretion of the court. *See Stallworth*, 558 F.2d at 263. When considering timeliness, the Fifth Circuit applies the following factors: 1) the length of time between the would-be intervenor's learning of his or her interest and the petition to intervene; (2) the extent of prejudice to existing parties from allowing late intervention; (3) the extent of prejudice to the would-be intervenor if the petition is denied; and (4) any unusual circumstances weighing in favor of or against intervention. *Stallworth,* 558 F.2d at 264Û66.

B. The 340B Program and 340B Drug Distribution

The 340B Program requires drug manufacturers to offer discounts on covered outpatient drugs to statutorily defined safety-net providers, referred to as "covered entities," as a condition of the manufacturers' drugs being reimbursed by Medicaid and Medicare Part B. 42 U.S.C. § 256b(a)(1); 42 U.S.C. § 1396r-8(a)(1). The Health Resources and Services Administration ("HRSA") within the federal Department of Health and Human Services is responsible for

administering the 340B Program. The 340B Program makes drugs more affordable for covered entities because those entities provide significant levels of uncompensated care, and the discounts available through the 340B Program help relieve that burden. Covered entities essentially lose less money on prescription drugs under the 340B Program for their uninsured and underinsured patients. And by avoiding these losses, they can be more generous with reducing or waiving patient co-payments at the pharmacy counter. The 340B Program also generates revenue for covered entities so that they are less dependent on taxpayer support. To the extent a covered entity patient has prescription drug coverage, the difference between the insurer's payment and the discounted price is income to the covered entity to supplement federal funds, thus allowing the covered entity to "stretch scarce federal resources as far as possible" and enabling it to "reach[] more eligible patients and provid[e] more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 11 (1992) (Conf. Rep.).

The Medicaid statute requires pharmaceutical manufacturers to provide rebates to state Medicaid programs on outpatient drugs and biological products furnished to Medicaid beneficiaries. 42 U.S.C. § 1396r-8. The 340B statute protects manufacturers from providing a 340B discount and a Medicaid rebate on the same drug. 42 U.S.C. § 256b(a)(5)(A). To comply with this requirement, some covered entities "carve out" Medicaid patients, which means that they do not dispense 340B drugs to Medicaid patients. *See Duplicate Discount Prohibition*, HRSA (July 2020) https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion/index.html. Other covered entities "carve in," which means that they dispense 340B drugs to Medicaid patients and notify the state Medicaid agency of their election to ensure that the state does not seek a Medicaid rebate from the manufacturers for those prescriptions. *Id.*

Most illnesses and injuries cannot be adequately treated or managed without the patient

taking one or more medications. That means providers of health care—such as LPCA's members—must ensure that their patients have access to a pharmacy to fill their prescriptions. For this reason, many providers own and operate their own pharmacies, often referred to as in-house pharmacies. However, because the construction and management of a pharmacy is expensive and requires special expertise, many providers contract with independently owned pharmacies to meet the pharmacy needs of their patients.[1] In most cases, these contract pharmacies are located in the provider's service area so that they are convenient and accessible to the provider's patients.[2] Typically, drugs dispensed by contract pharmacies are purchased under what is referred to as a "bill to/ship to" arrangement—the drugs are billed to the health care provider but shipped to the contract pharmacy. The provider-purchaser takes title to the drugs but does not take physical possession of the drugs. A wholesaler ships the drugs to the contract pharmacy, which takes physical custody of the drugs and dispenses them on the provider's behalf to the provider's patients.

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[1] *See, e.g.*, *How to Open a Pharmacy*, PioneerRX, https://www.pioneerrx.com/how-to-open-a-pharmacy (estimating that "opening a pharmacy will cost on average $400,000 to $600,000."); Sarah Shoemaker-Hunt et al., Cost of Dispensing Study (Jan. 2020), https://www.nacds.org/pdfs/pharmacy/2020/NACDS-NASP-NCPA-COD-Report-01-31-2020-Final.pdf (stating that the cost of dispensing non-specialty drugs at retail pharmacies ranges from $692,400, for a volume of 40,000 prescriptions a year, to $1,427,988.10, for a volume of 119,999 prescriptions a year, and that the cost of dispensing specialty drugs ranges from $294,320, for a volume of 40,000 prescriptions a year, to $882,952 for a volume of 119,999 prescriptions a year).

[2] Some medications, however, require special storage and handling and can only be dispensed by a specialty pharmacy through a mail order program. These specialty pharmacies are generally located outside the provider's service area. *See, e.g.*, Am. Soc'y of Health-Sys. Pharmacists, *ASHP Accreditation Standard for Specialty Pharmacy Practice* (July 2020), https://www.ashp.org/-/media/assets/products-services/ASHP-Accreditation-Programs/docs/Accreditation-Standard-Specialty-Pharmacy-Practice.pdf (noting that specialty pharmacy practice involves high cost drugs; complex treatment regimens requiring ongoing clinical monitoring and patient education infrastructure; specialty drug handling, storage, and delivery infrastructure; and other services required for complex high-touch disease states and treatments).

After passage of the 340B statute in 1992, it became abundantly clear that if covered entities did not possess the right to acquire drugs through bill to/ship to arrangements, many of them—specifically those lacking in-house pharmacies—would never be able to participate in the 340B Program, even though they clearly met the eligibility criteria established by Congress. HRSA issued guidance explicitly recognizing covered entities' existing right to use bill to/ship to arrangements for meeting the pharmacy needs of their patients. For nearly three decades, every drug company participating in the 340B Program, including Plaintiffs, honored bill to/ship to arrangements and treated contract pharmacies the same as in-house pharmacies. That changed abruptly, however, in July 2020 when one manufacturer after another either fully eliminated or significantly restricted distribution of 340B drugs ordered through bill to/ship to arrangements. *See* AbbVie, 340B Contract Pharmacy Data Integrity Initiative (Dec. 29, 2021), https://www.dropbox.com/s/toubic1o373h4gk/Abbvie_Covered%20Entity%20Letter%20340B%20Integrity%20Initative.pdf?dl=0. As of today, twenty-nine manufacturers have unilaterally imposed some type of restriction on contract pharmacy arrangements.[3] These restrictions have deprived covered entities of receiving the revenue and savings intended by Congress which, in turn, reduces the resources available to covered entities to meet the needs of their vulnerable patients, including the need for affordable and accessible prescription drugs.

Several drug manufacturers have sued HHS seeking to halt its enforcement against them regarding their contract pharmacy policies. These drug companies are AstraZeneca, Lilly USA,

[3] The following drug companies have restricted 340B drug distribution: AbbVie, Amgen, Inc., Astellas Pharma, Inc., AstraZeneca Pharmaceuticals LP, Bausch Health, Bayer, Biogen, Boehringer Ingelheim Pharmaceuticals, Inc., Bristol Myer Squibb, Eisai, Eli Lilly and Company, EMD Serono, Exelixis, Gilead Sciences, Inc., GlaxoSmithKline, Incyte, Jazz Pharmaceuticals, Johnson & Johnson, Merck and Company, Novartis Pharmaceuticals Corporation, Novo Nordisk, Inc., Organon & Co., Pfizer, Inc., Sandoz, Sanofi-Aventis US LLC, Takeda Pharmaceuticals, Teva Pharmaceuticals, UCB, and United Therapeutics Corporation.

LLC ("Lilly"), Novartis Pharmaceuticals ("Novartis"), Novo Nordisk, Sanofi, and United Therapeutics. The district courts have issued decisions in each case, and the parties have appealed those decisions. *AstraZeneca Pharm., LLC v. Becerra*, No. 21-27-LPS, 2022 WL 484587 (D. Del. Feb. 16, 2022); *Novartis Pharms. Corp. v. Espinosa*, No. 21-CV-1479, 2021 WL 5161783 (D.D.C. Nov. 5, 2021), *appeal docketed*, No. 21-5299 (D.C. Cir. Dec. 30, 2021); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health and Hum. Servs.*, No. 21-00634, 2021 WL 5150464 (D.N.J. Nov. 5, 2021), *appeal docketed*, No. 21-3168 (3d Cir. Nov. 26, 2021); *Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs*., No. 1:21-CV-00081, 2021 WL 5039566 (S.D. Ind. Oct. 29, 2021), *appeal docketed,* No. 21-3128 (7th Cir. Nov. 15, 2021). On January 30, 2023, the Third Circuit issued a decision that the contract pharmacy restrictions that Sanofi, Novo Nordisk, Inc., and AstraZeneca imposed are permissible under the 340B statute and not subject to enforcement actions by HHS. *Sanofi Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs*., 58 F.4th 696, 707 (3d Cir. 2023). The D.C. Circuit and Seventh Circuit have not yet issued decisions.

In May 2021, Arkansas enacted Act 1103, which, like Louisiana Act 358, requires drug companies to ship 340B discounted drugs to contract pharmacies. Ark. Code Ann. §§ 23-92-601–606. The Pharmaceutical Research and Manufacturers of America ("PhRMA") sued the state of Arkansas, challenging the contract pharmacy provisions of Act 1103 and arguing that the Arkansas law is preempted by the 340B statute. Compl., *Pharm. Rsch. & Mfgs. of Am. v. McClain*, 4:21-cv-00864-BRW (E.D. Ark. Sept. 29, 2021), ECF No. 1. Community Health Centers of Arkansas and Piggott Community Hospital moved to intervene as defendants. Mot. to Intervene, *Pharm. Rsch. & Mfgs. of Am. v. McClain*, 4:21-cv-00864-BRW (E.D. Ark. Mar. 28, 2022), ECF No. 17. The court held that these health care providers were entitled to intervention

of right and, had intervention as of right not been warranted, it would also have granted permissive intervention. Order Granting Mot. to Intervene, *Pharm. Rsch. & Mfgs. of Am. v. McClain*, 4:21-cv-00864 (E.D. Ark. May 3, 2022), ECF No. 22. On December 12, 2022, the Arkansas district court held that Act 1103 is not preempted. Order, *Pharm. Rsch. & Mfgs. of Am. v. McClain*, 4:21-cv-00864 (E.D. Ark. Dec. 12, 2022), ECF No. 48. PhRMA appealed to the Eighth Circuit Court of Appeals, which held oral argument on September 20, 2023. *Pharm. Rsch. & Mfgs. of Am. v. McClain*, No. 22-3675 (8th Cir. argued Sept. 20, 2023). The Eighth Circuit has not yet issued a decision.

C. Louisiana Act 358

Act 358 (codified at La. Stat. Ann. §§ 40:2881 to 2886 and titled the "Defending Affordable Prescription Drug Costs Act") includes La. Stat. Ann. § 40:2884(A) and (B), which protect 340B bill to/ship to arrangements for covered entities and pharmacies located and doing business in Louisiana. Consistent with the state's authority to regulate drug distribution to pharmacies within its borders, the statute regulates 340B drug distribution through two provisions. First, La. Stat. Ann. § 40:2884(A) prohibits a drug manufacturer from denying a covered entity access to 340B drugs if the covered entity uses contract pharmacy arrangements to participate in the 340B Program. Second, La. Stat. Ann. § 40:2884(B) prohibits a manufacturer from interfering with a Louisiana-based pharmacy contracted with a 340B covered entity. Section 40:2885 states that a violation of Act 358 is a violation of the Louisiana Unfair Trade Practices and Consumer Protection Law, La. Stat. Ann. § 51:1401 *et seq.*

On July 27, 2023, PhRMA filed suit in this Court, arguing that that two provisions of Act 358, codified at La. Stat. Ann. § 40:2884(A)–(B), are preempted by the 340B statute and are unconstitutionally vague. Compl., *Pharm. Rsch. & Mfgs. of Am. v. Landry*, No. 6:23-cv-00997-

RRS-CBW, ECF No. 1. On August 4, 2023, AstraZeneca filed suit in this Court, also arguing that Act 358 is preempted and additionally contending that it violates the Contracts Clause to the U.S. Constitution, U.S. Const. art. I, § 10. Compl., *AstraZeneca Pharm. LP v. Landry*, No. 6:23-cv-01042-RRS-CBW, ECF No. 1. LPCA moved to intervene in both cases, and this Court granted LPCA's motions. Order Granting Motion to Intervene, *Pharm. Rsch. & Mfgs. of Am. v. Landry*, No. 6:23-cv-00997-RRS-CBW, ECF No. 26; Order Granting Motion to Intervene, *AstraZeneca Pharm. LP v. Landry*, No. 6:23-cv-01042-RRS-CBW, ECF No. 29.

II. Factual Background

LPCA is a non-profit organization comprised of thirty-nine Louisiana-based community health centers that provide primary health care services in over three hundred service locations across the state. They treat large numbers of uninsured and underinsured low-income Louisianans because they are dedicated and legally obligated to care for anyone regardless of the patient's ability to pay. Each of LPCA's member health centers participates in the 340B Program by virtue of their receipt of federal funding under Section 330 of the Public Health Service Act. 42 U.S.C. §§ 254b, 256b(a)(4)(A); 42 U.S.C. § 1396d(l). These entities are referred to as Federally Qualified Health Centers ("FQHCs"). Importantly, Section 330 contains several requirements, including a requirement that health centers provide "pharmaceutical services as may be appropriate . . . ." 42 U.S.C. § 254b(b)(1)(A)(i)(V). Many of LPCA's thirty-nine health centers do not own their own pharmacies. Instead, they rely on outside community-based retail pharmacies to order, receive, and dispense self-administered medications for their patients.

ARGUMENT

LPCA is entitled to intervention as of right and satisfies the requirements for permissive intervention. LPCA is entitled to mandatory intervention because it has timely moved for intervention and has a significant, legally protectable interest in the outcome of this litigation, and that interest is not adequately represented by Defendant. In the alternative, LPCA should be granted permissive intervention because intervention will not unduly delay or prejudice an existing party, and LPCA's motion is timely and presents common questions of law and fact with the current litigation.

I. LPCA Is Entitled to Intervene as of Right

LPCA satisfies the Fifth Circuit's four-part test for intervention as of right, which is construed liberally. *Wal-Mart Stores*, 834 F.3d at 565; *In re Lease Oil Antitrust Litig.*, 570 F.3d at 248 ("Rule 24 is to be construed liberally, . . . and doubts resolved in favor of the proposed intervenor.") (citations omitted). LPCA has an interest in this litigation because its members rely on 340B contract pharmacies to receive and dispense needed medications for their patients, many of whom are uninsured, underinsured, or otherwise medically vulnerable. LPCA's interests will be impacted by the litigation because Act 358 protects the right of LPCA's members to use contract pharmacy arrangements for ordering, receiving, and dispensing 340B drugs. In addition, Defendant does not adequately represent LPCA's interests, which differ from, and in some respects conflict with, the Defendant's interests.

A. LPCA's Motion Is Timely

LPCA's motion is timely. First, litigation has not progressed substantially since Plaintiffs filed their First Amended Complaint on September 27, 2023. *Ass'n of Pro. Flight Attendants v. Gibbs*, 804 F.2d 318 (5th Cir. 1986) (finding timeliness when considering a five-month lapse). On December 11, 2023, the Court set a briefing schedule. Order Granting Joint Mot. To Set

Briefing Schedule, *AbbVie v. Landry*, 6:23-cv-01307 (W.D. La. Dec. 11, 2023), ECF No. 22. The Defendant is scheduled to file its cross motion for summary judgment on February 16, 2024, and LPCA is ready to meet that deadline.[4] In addition, Louisiana enacted Act 358 on August 1, 2023, and no implementing regulation has been promulgated. Granting intervention will cause no disruption or delay in the proceedings and will not prejudice existing parties. Therefore, the motion to intervene is timely under Rule 24(a).

B. LPCA Has an Interest Relating to the Property or Transaction That Is the Subject of This Action

LPCA has a direct and substantial interest in the outcome of this litigation because Act 358 protects its members' rights to enter into contract pharmacy arrangements to order and receive 340B drugs. *La Union del Pueblo Entero v. Abbott*, 29 F.4th 299, 305 (5th Cir. 2022) (holding that local and national committees had a "direct, substantial, [and] legally protectable interest" in challenging a bill amending the state code) (internal quotations omitted); *see also* Order Granting Mot. to Intervene at 6, *Pharm. Rsch. & Mfgs. of Am. v. McClain*, 4:21-cv-00864 (E.D. Ark. May 3, 2022), ECF No. 22 ("Because Intervenors have demonstrated recognizable economic interests in the present lawsuit [challenging Arkansas Act 1103], their alleged interests … are sufficiently direct, substantial, and legally protectable to allow them to intervene in the case."). LPCA has a significant, legally protectable interest in this lawsuit because its primary mission of providing services to Louisiana's most vulnerable patients would be threatened if this Court invalidated Act 358. *Wal–Mart Stores*, 834 F.3d at 569 (finding intervention permissible

[4] On Jan 11, 2024, LPCA sought Plaintiffs' position on its intervention motion, and LPCA sent Plaintiffs the motion and a draft of this brief on January 16, 2024. The Parties conferred by telephone on January 19, 2024, and Plaintiffs informed LPCA of their position on LPCA's motion later that day. LPCA filed its intervention motion on January 19, 2024 after learning Plaintiffs' position. The timing of this motion was impacted, in part, by these discussions between LPCA and Plaintiffs.

when an association's primary mission was impeded). LPCA's members rely heavily on contract pharmacies to provide 340B medications to uninsured and underinsured Louisiana patients at little or no cost. Thus, LPCA has an interest in the Court upholding Act 358 because Act 358 addresses drug manufacturer restrictions on distribution of drugs to contract pharmacies.

LPCA's interests are not "remote or contingent." *Ross v. Marshall*, 426 F.3d 745, 758 (5th Cir. 2005). Until July 2020, every drug manufacturer participating in the 340B Program recognized a 340B covered entity's right to dispense its 340B drugs through an unlimited number of contract pharmacies. Now, twenty-nine drug manufacturers—including Plaintiff AbbVie—have implemented policies that restrict distribution of 340B drugs to contract pharmacies. *See 340B ESP Resources*, 340B ESP, https://www.340besp.com/resources (last visited Jan. 16, 2024). The manufacturer policies differ, often including complicated exceptions or conditions. AbbVie's current policy applies only to 340B covered entities that are hospitals and does not currently apply to LPCA's members. Manufacturers, however, frequently change their contract pharmacy restrictions, including by expanding the categories of covered entities to which the restrictions apply.[5] And other manufacturers do have contract pharmacy restrictions applicable to LPCA's members. Thus, LPCA's members face an imminent threat of significant financial harms that Act 358 is intended to prohibit. Plaintiffs' challenge to this law, if successful, would allow drug manufacturers to *continue* to prevent distribution of 340B drugs purchased by Louisiana covered entities for dispensation at contract pharmacies. *La Union del*

[5] For example, prior to November 1, 2023, Bristol Myers Squibb imposed contract pharmacy restrictions only on hospital covered entities but revised its policies effective November 1, 2023 to apply to all covered entities. *Compare* Email from Bristol Myers Squibb to 340B Customers (Jan. 14, 2022), https://www.340bhealth.org/files/Bristol_Myers_Squibb_email_01-14-22.pdf *with* Notice Regarding Bristol Myers Squibb 340B Practice, Bristol Myers Squibb (Oct. 6, 2023), https://www.340besp.com/BMS_CE_Letter.pdf.

Pueblo Entero, 29 F.4th at 306Û07 (permitting intervention based on an interest contingent upon the "outcome of [a] lawsuit"). LPCA has a substantial and protectable interest in safeguarding the interests of its members and their patients.

C. LPCA's Interests Will Be Impaired by the Disposition of the Litigation

Plaintiffs ask this Court to invalidate Act 358 and the protections that it affords to all covered entities to have 340B drugs distributed to contract pharmacies. Without intervention, disposition of the current action will "as a practical matter impair or impede" LPCA's interests. *Brumfield*, 749 F.3d at 341; *see also* Order Granting Mot. to Intervene at 6, *Pharm. Rsch. & Mfgs. of Am. v. McClain*, 4:21-cv-00864 (E.D. Ark. May 3, 2022), ECF No. 22. A court order invalidating Act 358 would permit manufacturers to restrict or eliminate contract pharmacy shipments ordered by FQHCs.

Many LPCA members do not operate in-house pharmacies and rely exclusively on outside, community-based retail pharmacies to order, receive, and dispense 340B drugs. This is because the requirements to obtain a pharmacy license are complex and operating an in-house pharmacy is expensive. Without the ability to order, receive, and dispense self-administered drugs at 340B discounts through contract pharmacies, LPCA members cannot meet the pharmacy needs of their patients. If this lawsuit is decided in favor of Plaintiffs, LPCA members and other 340B covered entities in Louisiana will be at the mercy of drug manufacturers that prohibit or severely restrict their ability to order and receive 340B drugs at contract pharmacies. *See Brumfield*, 749 F.3d at 344 (proposed intervenor must show that interest "may" be impaired or impeded by litigation).

LPCA members use 340B savings and revenue from drugs shipped to contract pharmacies to provide vital safety-net services to impoverished patients and communities.

Contract pharmacies are, therefore, a vital component of Louisiana's public health care system. The refusal of drug companies to distribute 340B drugs to contract pharmacies will result in financially needy patients no longer having access to discounted drugs which, in turn, will likely cause them to forgo prescribed medications or request less costly medications that may not be as efficacious. Moreover, LPCA's members will be forced to reduce or eliminate the services that they provide to patients, resulting in harm to their patients and the need for more expensive health care services. Striking down Act 358 would cause a serious hardship to LPCA members and their vulnerable patients as well as other 340B providers and their patients. *Sierra Club v. Espy*, 18 F.3d 1202, 1207 (5th Cir. 1994) (intervenor successfully showed that its interests may be impaired by the operation of stare decisis effect of the result of the litigation).

D. LPCA's Interests Are Not Adequately Protected by the Parties

Plaintiffs, which seek to invalidate Act 358, plainly do not represent the interests of LPCA. Although LPCA's interest in defending and enforcing Act 358 may appear to align with the interests of the Defendant, the Defendant also does not adequately represent the interests of LPCA and its members.[6] *See Brumfield*, 749 F.3d at 346; *Texas*, 805 F.3d at 662. Defendant has not yet promulgated rules to implement Act 358, and LPCA is not aware that Defendant has taken any enforcement actions against drug companies that are violating Act 358. Furthermore, Defendant has a policy that actually *limits* 340B discounts for drugs dispensed by contract pharmacies. La. Dep't of Health, Bull. No. 16-9, 340B Policy Clarification (Jan. 6, 2023)

[6] An intervenor does not have to establish standing. *Texas v. United States*, 805 F.3d 653, 659 (5th Cir. 2015) ("[A]lthough an asserted interest must be legally protectable [to support intervention as of right], it need not be legally *enforceable*. In other words, an interest is sufficient if it is of the type that the law deems worthy of protection, even if the intervenor does not have an enforceable legal entitlement or would not have standing to pursue her own claim.") (internal quotations omitted). LPCA nonetheless has standing because its members are injured by the conduct that Louisiana Act 358 is intended to remedy.

https://ldh.la.gov/assets/docs/BayouHealth/Informational_Bulletins/16-09/IB16-09_revised_01.06.23.pdf. Defendant's policy prohibits covered entities from dispensing 340B drugs to fill prescriptions for Medicaid beneficiaries at contract pharmacies. *Id.* This policy has the effect of increasing the state's Medicaid rebates but eliminating 340B discounts to covered entities for these prescriptions. Defendant's interests are not, therefore, wholly aligned with LPCA members' interests. LPCA meets the "minimal" burden, which "'is satisfied if [LPCA] shows that representation of [its] interest may be inadequate.'" *Haspel & Davis Milling & Planting Co. v. Bd. of Levee*, 493 F.3d 570, 578 (5th Cir. 2007) (quoting *Edwards v. City of Houston*, 78 F.3d 983, 1005 (5th Cir.1996) (en banc)); *see also* Order Granting Mot. to Intervene at 6û7, *Pharm. Rsch. & Mfgs. of Am. v. McClain*, 4:21-cv-00864 (E.D. Ark. May 3, 2022), ECF No. 22 ("Defendants have a broad interest in protecting the constitutionality of duly enacted state laws and the state's ability to enforce these laws, but Intervenors have a specific economic interest regarding Act 1103. On this basis, Intervenors have demonstrated that their interests are sufficiently disparate from the current Defendants so that their interests will not be adequately protected by the existing parties to this lawsuit.").

Finally, LPCA can provide the Court with the unique perspective of community-based 340B covered entities, the entities that Act 358 was enacted to protect. LPCA can explain how access to 340B drugs through contract pharmacies benefits the patients that LPCA's members serve. LPCA can, therefore, provide the Court with the perspective of Louisiana-based 340B covered entities that depend on contract pharmacies, a perspective which neither Plaintiffs nor Defendant can offer because they are not health care providers.

II. LPCA Satisfies the Standards for Permissive Intervention Under Rule 24(b)(2)

In addition to meeting the requirements for intervention as a matter of right under Rule

24(a), LPCA meets the requirements for permissive intervention under Rule 24(b). LPCA "shares with the main action a common question of law or fact" regarding the legality of Act 358. Fed. R. Civ. P. 24(b)(1)(B). LPCA has a claim or defense that is timely and will not unduly prejudice or delay the adjudication of the parties' rights. *See* Order Granting Mot. to Intervene at 7, *Pharm. Rsch. & Mfgs. of Am. v. McClain*, 4:21-cv-00864 (E.D. Ark. May 3, 2022), ECF No. 22 (holding that permissive intervention is warranted).

A. Intervention Will Not Cause Undue Delay or Prejudice

Allowing LPCA to intervene will not result in undue delay or prejudice to the other parties in the lawsuit. Fed. R. Civ. P. 24(b)(3); *Newby*, 443 F.3d at 416. The Fifth Circuit has made clear that prejudice to existing parties, "must be measured by the delay in seeking intervention, not the inconvenience to the existing parties of allowing the intervenor to participate in the litigation." *Rotstain*, 986 F.3d at 939; *see also Sierra Club*, 18 F.3d at 1206. Plaintiffs only filed their summary judgment motion on January 12, 2024, and the Defendant has not yet filed a dispositive motion. LPCA is ready to participate fully and actively in this case and will comply with the briefing schedule that the Court set on Dec. 11, 2023. Order, ECF No. 22. Thus, LPCA's motion for intervention is timely and intervention will not cause delay or prejudice.

B. LPCA Brings a Claim or Defense That Shares a Common Question of Law or Fact

LPCA should be permitted to intervene because it brings a timely claim or defense and "shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1)(B). "[T]he 'claim or defense' portion of Rule 24(b)(2) has been construed liberally." *Newby*, 443 F.3d at 422 (citing *In re Estelle*, 516 F.2d 480, 485 (5th Cir. 1975)); *see also United States ex rel. Hernandez,* 80 F.4th at 577. LPCA's claim falls within the definition of "claim"—an "interest or

remedy recognized at law." *United States ex rel. Hernandez,* 80 F.4th at 577 (quoting *Claim,* Black's Law Dictionary (11th ed. 2019)).

An intervenor can generally meet the commonality requirement if it demonstrates that it shares a similar goal in litigating the issue or the principal action arises from a similar set of facts. *See id.* at 578. Here, LPCA's defenses are sufficiently intertwined and based on the same set of facts pled in Plaintiffs' complaint concerning the legality and constitutionality of Act 358. LPCA also shares a common question of law—whether Act 358 is lawful—and will not interject collateral issues. *See id*. ("We also conclude that [Intervenor's] claim shares a common question of law with the district court's decisions . . . .").

CONCLUSION

For the foregoing reasons, LPCA respectfully requests that the Court grant its motion to intervene as of right under Rule 24(a) or, in the alternative, to allow it to intervene under Rule 24(b).

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Respectfully submitted,

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